

REMARKS

The application is subject to a restriction requirement. The Examiner requires restriction among the alleged Groups and Species of the claimed invention as shown in claims 1-28. The Examiner cites only PCT Rules as the reasons for restricting the current claims into separate groups. The restriction is respectfully traversed on two separate bases: 1.) the Restriction form is improper; and 2.) a search of claims 1-28 would not impose a serious burden on the Examiner. For these reasons, withdrawal of the restriction requirements is respectfully requested.

In an Interview with Examiner Sheikh dated July 2, 2009, Applicant articulated to the Examiner that the present restriction which relies on PCT Rules is improper and not in compliance with the MPEP or U.S. Code which provide the basis for restriction practice and patent prosecution in the United States. Although it may be common practice for Examiners to rely upon PCT Rules for determining a restriction requirement in a U.S. application, it is in fact wrong to do so.

Assuming *arguendo*, that a restriction requirement in a U.S. case which cites PCT Rules is proper, then the Examiner would likely rely upon the International Search Report (ISR) and/or the invitation to pay additional search fees (if any) in the restriction requirement. These forms, common to PCT practice, would clearly articulate whether the application lacked unity of invention in light of the PCT Rules, and would set forth clearly defined groups pursuant to the PCT Rule 13.1.

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Here, the Examiner relies upon PCT Rule 13.1 and 13.2 in alleging that claims 1-28 lack unity of invention. However, upon review of corresponding the PCT application and prosecution, no invitation to pay additional search fees for additional inventions was issued in this case. Also, all claims were searched by the International Search Authority (ISA) without restriction. Further, the United States Patent and Trademark Office was the ISA, the entity which searched each and every claim for the present invention. It is improper to cite PCT Rules in a U.S. restriction requirement when there was no unity of invention issue identified in the corresponding PCT application by the ISA. No invitation to pay additional fees to search distinct inventions (grouped by claims) exists for this case. Further, the ISR is silent with respect to any unity of invention issues in the present case.

As Examiner Sheikh rightfully pointed out in the previously referenced telephone interview, the United States has different standards and guidelines for patent prosecution than the Patent Cooperation Treaty. For this reason, the Restriction Requirement alleging more than one invention is present in claims 1-28 should be based upon U.S. law and not rules of the PCT.

The Examiner has attacked the claims with a restriction/election requirement citing the PCT Rules. At the same time, the Examiner has stated that the international search report conducted by the U.S. carries no weight in U.S. practice and the contents of the report are not determinative of whether more than one invention is present in U.S. practice. These statements, made by an authorized representative of the USPTO, are contradictory and provide for ambiguous, unclear, and confusion restriction/election practice. For these reasons, an Examiner

cannot rely upon the PCT Rules and practice as both a shield and a sword in the present U.S. restriction/election office action. To allow such practice mandates practitioners to draft poorly reasoned and unsupported responses that cite and rely upon PCT practice, which is different and distinct from U.S. law.

Applicant respectfully asserts that it is necessary to clarify the record of the present invention and rely upon U.S. Code in the office action detailing a restriction/election requirement in order to prevent the possibility of undue ambiguous construction of the file history at a future date. Correcting the record now may result in quality compliance and one or more stronger patents, in general, by eliminating confusion of the laws and acceptable practice of the U.S. on the record.

In view of this, Applicant requests that withdrawal of the previous action in favor of an action that relies upon the U.S. code. As the Examiner has instructed Applicant in the July 2, 2009 interview to respond in full to the current restriction requirement and cite the above-referenced request and reasoning in that response, below, please find the details of the restriction/election requirement.

The Examiner requires election among the following inventions, in view of PCT Rule 13.1, as follows:

Group I: claims 1-20, drawn to an oral dosage delivery vehicle (class 424/401, 439);

Group II: claims 21-26, drawn to a package (class 206/438, 449, 484); and

Group III: claims 27 and 28, drawn to a process of making and process of using class 264/172.19; 156/308.4).

Applicant elects to prosecute Group I, claims 1-20, with traverse.

The Examiner also requires an election of species for prosecution on the merits pursuant to PCT Rule 13.1, as follows:

Species A: dosage without active ingredient (see claim 11); and

Species B: dosage with active ingredient (see claims 16-17).

Applicant provisionally elects with traverse, Species B. Applicant respectfully submits that claims 1-10, 16-17, and 19-20 read on the election of Group I, Species B.

In addition to technical inaccuracy and public policy considerations, MPEP § 803 provides further grounds for traversal of the restriction/election requirement. MPEP § 803 provides that although claims to distinct or independent inventions may exist, examination on the merits is required provided that the search can be made without serious burden. Applicant asserts that no such burden exists with a search of claims 1-28, as presently set forth. In fact, the search has already been conducted by the International Bureau.

It is respectfully submitted that the Examiner would certainly search the claims in Group III to find a reference against the species of any of Groups I and vice versa, as each comprises an active ingredient. Similar arguments apply for claims in Group II. Accordingly, Applicants maintain that a co-extensive field of search seems virtually mandated and would not present an undue burden.

Furthermore, Applicants respectfully request that upon indication of allowance of the claims of the elected species, Applicant respectfully requests allowance of the claims directed

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towards the non-elected, generic species. Applicant reserves the right to pursue the non-elected subject matter in one or more divisional applications.

For the reasons set forth above, Applicants respectfully request that the requirement for election be withdrawn and consideration of all of the claims on the merits be commenced.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,

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